In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 26, 2025

MORGAN TIRONE,	*	PUBLISHED
Petitioner,	*	No. 18-869V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal; Severity Requirement; Meningococcal ("Menactra") Vaccine; Pneumococcal Conjugate ("Prevnar 13") Vaccine; Fibromyalgia.
Respondent.	*	

Mark Theodore Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner.
Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On June 19, 2018, Morgan Tirone ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018),[2] alleging that she suffered from injuries, including Guillain-Barré acute infective polyneuritis, demyelinating neuropathy, post-vaccination syndrome, post-vaccination fever, and/or serum sickness as a result of receiving the meningococcal ("Menactra")

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) ("Vaccine Act" or "the Act"). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

vaccine[3] and pneumococcal conjugate ("Prevnar 13") vaccine on June 29, 2015.[4] Petition at Preamble (ECF No. 1). Petitioner received a third vaccination, the 23-valent pneumococcal polysaccharide ("Pneumovax 23")[5] vaccine, on August 24, 2015. Id. at ¶ 5. Respondent argued against compensation, stating "this case is not appropriate for compensation under the terms of the [Vaccine] Act." Respondent's Supplemental Report ("Resp. Rept."), filed Oct. 23, 2020, at 3 (ECF No. 56).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards,[6] the undersigned finds Petitioner has failed to provide preponderant evidence that vaccines covered under the Vaccine Act, Menactra and Prevnar 13, caused her alleged injury of FM.[7] Thus, Petitioner has failed to satisfy her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Additionally, Petitioner has failed to meet the severity requirements under the Vaccine Act. § 11(c)(1)(D)(i)–(iii). Accordingly, the petition must be dismissed.

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[3] Although Petitioner alleges that Menactra is a causal vaccine, the focus of her expert's opinions is the Prevnar 13 vaccine. See Petitioner's Exhibits ("Pet. Exs.") 15, 48.

[4] Petitioner subsequently modified her alleged injuries to fibromyalgia ("FM") in her expert reports and her motion for a ruling on the record. Petitioner's Exhibit ("Pet. Ex.") 15 at 2 ("[Petitioner] develop[ed] [FM] as a result of over-doctoring and lack of counseling."); Pet. Ex. 48 at 1 ("I believe her diffuse complaints [of pain] are consistent with a pain threshold disorder of which [FM] is the most likely candidate."); Pet. Motion for Ruling on the Record ("Pet. Mot."), filed Dec. 20. 2023, at 6-13 (ECF No. 129) (arguing Petitioner's FM was the result of vaccination); Pet. Reply to Respondent's Response to Pet. Mot. ("Pet. Reply"), filed June 12, 2024, at 1 (ECF No. 140) ("The parties agree . . . that [Petitioner] ultimately suffered from [FM].").

[5] Pneumovax 23, a polysaccharide-type pneumococcal vaccine, is a noncovered vaccine. See 42 C.F.R. § 100.3; see also, e.g., Cielencki v. Sec'y of Health & Hum. Servs., No. 15-632V, 2015 WL 10767150, at *2 (Fed. Cl. Spec. Mstr. Dec. 22, 2015). Therefore, any condition allegedly caused by Pneumovax 23 is not compensable.

[6] While the undersigned has reviewed all the information filed in this case, only those filings and records that are most relevant will be discussed. See Moriarty v. Sec'y of Health & Hum. Servs., 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision."); see also Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

[7] Petitioner narrowed her injury to FM to reflect her medical records, treating physician opinions, and expert's opinions, specifically the opinions of Dr. Gershwin. See Pet. Exs. 15, 48; supra note 4.

I. ISSUES TO BE DECIDED

In their joint submission, the parties identify three factual issues that require resolution—diagnosis, onset, and duration of Petitioner's injury. Joint Submission ("Joint Sub."), filed Oct. 26, 2023, at 1 (ECF No. 125).

Regarding diagnosis, Petitioner alleges that her injury is FM, and Respondent does not dispute an FM diagnosis. Pet. Reply at 1 ("The parties agree . . . that [Petitioner] ultimately suffered from [FM]."); Respondent's Response to Pet. Mot. ("Resp. Response"), filed Mar. 21, 2024, at 2, 18 (ECF No. 133) (acknowledging that Petitioner's alleged injury is FM and noting "the parties seem to agree that [P]etitioner ultimately suffered from [FM]").

However, Respondent explains that the diagnosis dispute is not over Petitioner's ultimate diagnosis of FM, but rather "the nature of [P]eitioner's initial reaction to both the Prevnar 13 and Pneumovax 23 vaccines."[8] Resp. Response at 18. Specifically, Respondent asserts that "Petitioner insists she suffered allergic reactions, while [R]espondent maintains . . . that [P]etitioner suffered local injection site reactions." Id. (citing Pet. Mot. at 6 n.1). Thus, the diagnosis issue is whether Petitioner suffered either an allergic reaction or local injection site reactions to her Prevnar 13 vaccination.

Next, the parties dispute the onset and the duration of Petitioner's alleged vaccine injury. Joint Sub. at 1. Regarding duration, the question is whether Petitioner suffered the "residual effects or complications of [her alleged injury] for more than [six] months" after vaccination. Id. (citing § 11(c)(1)(D)(i)).

The parties also dispute causation, specifically whether the June 29, 2015 Menactra or Prevnar 13 vaccines can cause FM, or did cause Petitioner's alleged FM, and if so, whether onset occurred within a medically acceptable timeframe. Joint Sub. at 2.

II. BACKGROUND

A. Medical Terminology

FM is a common "disorder of widespread pain, tenderness, fatigue, sleep disturbance, and psychological distress." Pet. Ex. 16 at 1.[9] The estimated prevalence is 2% of adults, and it

[8] Because Pneumovax 23 is not a covered vaccine, the undersigned lacks statutory authority to resolve the question of what reaction occurred after it was administered. § 12(a) ("[T]he United States Court of Federal Claims special masters shall . . . have jurisdiction over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the Program."); see § 11(c)(1) (requiring a petition to contain "a vaccine set forth in the Vaccine Injury table").

[9] Frederick Wolfe et al., The Prevalence and Characteristics of Fibromyalgia in the General Population, 38 Arthritis & Rheumatism 19 (1995).

affects women at higher rates (3.4% women as compared with 0.5% men). Pet. Ex. 17 at 4.[10] The condition is associated with "multiple somatic complaints, depressive and anxiety symptoms" and "[d]epressive and anxiety symptoms are common and frequently severe." Id. at 5. The cause of FM is "unknown, although genetic and environmental facts probably contribute." Id. at 9. There is also evidence that FM may involve "augmentation of central pain processing." Id. at 13.

B. Procedural History

On June 19, 2018, Petitioner filed a petition, followed by medical records and Petitioner's affidavit in July 2018. Petition; Pet. Exs. 1-13. Respondent filed a Rule 4(c) report on March 7, 2019, arguing against compensation. Respondent's Report, filed Mar. 7, 2019, at 1 (ECF No. 18). In October 2019, the case was reassigned to the undersigned. Order dated Oct. 3, 2019 (ECF No. 28).

Between May 2019 and March 2021, Petitioner filed additional medical records, affidavits, and documentation, depositions, and transcripts from her workers' compensation claim as well as an expert report from Dr. M. Eric Gershwin. Pet. Exs. 14-15, 36-47. Petitioner was unable to obtain proof of vaccination records. Pet. Exs. 39-41. On October 22, 2020, Respondent filed an amended Rule 4(c) report reiterating that the case was not appropriate for compensation. Resp. Rept. at 1.

On April 13, 2021, the undersigned held a Rule 5 conference regarding proof of vaccination and recommended Respondent subpoena vaccination records from Petitioner's employer. Rule 5 Regarding Proof of Vaccination and Scheduling Order dated Apr. 13, 2021 (ECF No. 75). On July 22, 2021, Respondent filed proof of vaccination records. Resp. Exs. A-C.

On November 5, 2021, Respondent filed an expert report from Dr. Mehrdad Matloubian. Resp. Ex. D. The undersigned held a second Rule 5 conference on January 6, 2022 and allowed the parties to file additional expert reports. Rule 5 Order dated Jan. 6, 2022, at 3 (ECF No. 94). Petitioner filed a supplemental report from Dr. Gershwin on July 22, 2022, and Respondent filed a supplemental report from Dr. Matloubian on September 26, 2022. Pet. Ex. 48; Resp. Ex. F.

On July 27, 2023, Petitioner filed a joint status report reporting that the parties wished to resolve entitlement through a ruling on the record. Joint Status Rept., filed July 27, 2023 (ECF No. 119). Petitioner filed a motion for ruling on the record on December 20, 2023. Pet. Mot. Respondent filed a responsive brief on March 21, 2024. Resp. Response. On June 12, 2024, Petitioner filed her reply. Pet. Reply.

This matter is now ripe for adjudication.

[10] Lesley M. Arnold, The Pathophysiology, Diagnosis and Treatment of Fibromyalgia, 33 Psychiatric Clinics N. Am. 375 (2010).

C. Factual History

1. Summary of Medical Records[11]

Petitioner was 25 years of age at the time of the vaccinations at issue. Pet. Ex. 5 at 1. She had previously received vaccinations for Hepatitis B ("Hep B"), meningitis, measles, mumps, and rubella ("MMR"), and diphtheria, tetanus and pertussis ("Tdap"), without documented adverse reaction. Id. at 1-2.

Before her June 29, 2015 vaccinations, Petitioner's medical history was significant for exercise-induced asthma; allergies to penicillin, azithromycin, and strawberries; and shoulder and neck pain for which she sought chiropractic care beginning in September 2014. See, e.g., Pet. Ex. 5 at 1, 4, 6, 10, 13 (noting asthma and allergies); Pet. Ex. 14 at 77-91 (documenting chiropractic treatment).[12] On an intake questionnaire dated June 26, 2015, three days prior to the Menactra and Prevnar 13 vaccinations, she recorded having "[s]houlder/[n]eck pain," which she described as sharp, dull, and throbbing, with numbness, aching, shooting, burning, tingling, cramps, and stiffness "[a]ll the time." Pet. Ex. 14 at 87.

On June 29, 2015, Petitioner received Menactra and Prevnar 13 vaccines at Sanofi Pasteur ("Sanofi"), where she was employed as a lab analyst. Resp. Ex. A at 1-2.[13] There is no

[11] The summary of medical records was largely taken from Respondent's Response as the undersigned finds that it accurately recounts Petitioner's medical records and other documents. Resp. Response at 4-14. The undersigned has made edits to the summary. Further, the undersigned has reviewed all of Petitioner's medical records but for the sake of brevity only summarizes those most relevant to the issues herein.

[12] Petitioner treated with this chiropractor from September 2014 through January 2016. The chiropractic records, which are handwritten and generally illegible, were initially filed as part of Petitioner's workers' compensation claim. On October 23, 2020, the undersigned ordered Petitioner file legible and complete copies of these records. Order dated Oct. 23, 2020 (ECF No. 57). Petitioner ultimately was unable to obtain complete and legible records, as the chiropractor's license was revoked, and the location of his records was unknown. See Pet. Ex. 43 (affidavit regarding efforts to obtain records); Pet. Ex. 44 (chiropractic license revocation); Pet. Ex. 45 (article regarding chiropractic license revocation).

[13] Petitioner averred in her affidavit that she received Menactra in her right arm and Prevnar 13 in her left arm. Pet. Ex. 11 at ¶ 7. But the vaccination record does not contain sites of administration. See Resp. Ex. A at 1-2.

indication in the employee records provided by Sanofi, or Petitioner's medical records, that she reported any symptoms after the June 29, 2015 vaccinations.[14] See Resp. Ex. B at 1-3.

On August 24, 2015, Petitioner received a Pneumovax 23 vaccine at Sanofi. Resp. Ex. A at 2.[15]

On August 25, 2015, Petitioner presented to her primary care provider, Lillian Theune, D.O., complaining of neck and back pain, severe headache, hives, and an adverse reaction to Pneumovax 23 given the day before. Pet. Ex. 5 at 19-21. Petitioner reported that she received Prevnar 13 eight weeks earlier, after which "her arm was extremely sore and she could not lift it without pain." Id. at 19. She further reported that she received "Prevnar 23 [sic]" the day before. Id. Review of symptoms was positive for fever, but negative for nausea and fatigue. Id. at 20. Petitioner reported a rash at the site, fever, headache, and back pain. Id. at 19. Petitioner's temperature was 101.3ºF in the office. Id. at 20. Examination was normal except for multiple hives on the left upper arm at the alleged site of the injection. Id. The assessment was allergic reaction, and Dr. Theune prescribed a prednisone taper and recommended Benadryl as needed. Id. at 21.

On August 31, 2015, Petitioner returned to Dr. Theune with "upper respiratory tract symptoms which began [one] week ago." Pet. Ex. 5 at 40. She also complained of fever, headache, chills, and neck pain. Id. Petitioner reported that she improved on steroids, but her symptoms never completely resolved. Id. The examination was normal with no rashes present, and Petitioner was afebrile. Id. at 41-42. Dr. Theune noted that Petitioner had normal range of motion ("ROM") in her neck but had some "pain radiating down [her] spine" with neck flexion. Id. at 42. She sent Petitioner to the emergency room ("ER") for bloodwork and a possible spinal tap. Id.

Later that day, Petitioner presented to the ER at Hackettstown Medical Center and reported that she had received Pneumovax 23 "last week" and had a fever with body aches "right after getting it." Pet. Ex. 2 at 29. Her pain screening documented that the pain started "one week" ago and was a four on a zero to 10 pain scale. Id. at 31. Petitioner was alert and oriented

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[14] Petitioner averred in her affidavit that after receiving the June 29, 2015 vaccinations, "raised hives began to form on [her] left arm . . . accompanied by pain and swelling." Pet. Ex. 11 at ¶ 8. She further stated that these symptoms lasted "for about a week," and that she reported them "to the Lab Coordinator at Sanofi Pasteur but was told that the arm swelling and pain was 'normal.'" Id. at ¶¶ 7-8.

[15] In her affidavit, Petitioner implies that she received Pneumovax 23 in her left arm, but the vaccination record does not contain the site of administration. See Pet. Ex. 11 at ¶ 13; Resp. Ex. A at 2. Petitioner stated that "[i]mmediately after the vaccine was administered," her left arm began to burn. Pet. Ex. 11 at ¶ 13. She further stated that within two hours, she had the same rash on her left arm, was nauseous, and felt very fatigued. Id. On May 9, 2016, Petitioner told Dr. John Cohn, a physician who evaluated her for her workers' compensation claim, that the week prior to this vaccination, "she had much nausea, which she attributed to a '24 hour bug,'" and that she went home after work on August 24, 2015 and "tried to exercise." Pet. Ex. 14 at 23.

and her behavior was described as "appropriate, calm, [and] cooperative." Id. at 32. The pain "started after getting vaccine per [patient] last week." Id. at 33. The pain was gradual, constant, and achy. Id. The chief complaint description noted that her doctor had prescribed prednisone, that she had a fever all week, and her temperature was 99.9ºF that morning. Id. at 33. Petitioner also reported that

> [s]ince receiving Prevnar 13 [eight] weeks ago[, she] ha[d] developed swelling and pain in the [left upper extremity] at the inoculation [site] causing her to have occasional paresthesias in the fingertips and difficulty moving the arm. [Petitioner] also note[d] that a few hours after receiving [P]neumovax [one] week ago she developed [a] headache, body aches and hives associated with minimal chest and sinus congestion. [She] ha[d] had intermittent fevers since with constant headache and body aches.

Id. at 34. Petitioner complained of slight nausea and mild pain at the back of the neck, which radiated to her mid and lower back, was exacerbated by neck flexion and movements of the extremities, and was sometimes associated with distal extremity paresthesias. Id. She reported that "her employer had her mopping floors the day after the onset of symptoms." Id. Petitioner indicated that her rash had improved but her neck and back pain remained. Id. Petitioner's temperature in the ER was 97.9ºF. Id.

Examination revealed mild discomfort in the posterior neck and back with flexion, but full ROM, no rash, and no swelling of the extremities. Pet. Ex. 2 at 35. Petitioner's bloodwork showed an elevated white blood cell count, but was otherwise normal, including her sedimentation rate. Id. at 60. The differential diagnosis was a strain or vaccine reaction. Id. at 35. The ER doctor noted that he "[s]poke with Dr. Theune. Agree [symptoms] due to adverse [reaction] to vaccine." Id. The ER doctor prescribed prednisone. Id. at 36. The discharge diagnosis was adverse reaction to Pneumovax 23. Id.

On September 5, 2015, Petitioner presented to the ER at Morristown Medical Center for joint pain and swelling since getting the Pneumovax 23 vaccine. Pet. Ex. 10 at 220-23. She reported that immediately after the injection two weeks prior, she had a headache, pain at the injection site, and body aches. Id. at 221. She complained of persistent fevers since six days after vaccination, a headache beginning five days earlier, neck pain, and new joint pain beginning the date of this ER visit. Id. at 221-22. Petitioner had slight redness of the left lateral arm, but no fever, and her examination was otherwise normal. Id. at 222. The assessment was myalgia, and she was advised to stop prednisone. Id. at 220, 223.

On September 7, 2015, Petitioner presented to the ER at St. Joesph's Regional Medical Center with joint pain "all over." Pet. Ex. 5 at 51-55. She was afebrile and physical examination was normal. Id. at 52-54. Her white blood cell count was elevated at 21.3 k/mm3 (normal range 4.5-11.0 k/mm3). Id. at 62. The impression was polymyalgia rheumatica ("PMR"), and Petitioner received IV Solu-Medrol and a steroid taper and was discharged. Id. at 54-55.

From September 9 to 11, 2015, Petitioner was admitted to St. Joesph's Regional Medical Center after presenting with a fever, jaw pain, and numbness in her hands. Pet. Ex. 3 at 1-2, 227-

28. On admission, Petitioner's temperature was 100.8ºF, but her fever resolved with ibuprofen. Id. at 230-31, 239. On the date of admission, Petitioner's white blood cell count was elevated at 16.1 k/mm3 but it returned to normal by discharge. Id. at 15. On September 10, 2015, neurologist Steve Lequerica, M.D., consulted. Id. at 46-47. Petitioner reported that she was well until approximately August 24, 2015, when, after receiving Pneumovax 23, she "began having soreness in the injection site and nausea and chills with pain in the left hand with low-grade fevers." Id. at 46. She had increasing pain and numbness over the past week, particularly in her right hand. Id. Petitioner also reported that she had a vaccine at the end of June with local soreness but no systemic symptoms. Id. She complained of a persistent low-grade fever, and periods of headache and spine pain. Id. On examination, her temperature was 96.6ºF, she had no objective weakness, had 1+ reflexes throughout, and had subjective decreased sensation in the right hand. Id. Dr. Lequerica noted, "Her history and symptoms suggest a post-vaccination syndrome that is prolonged." Id. He ordered magnetic resonance imaging ("MRI") of the brain and cervical and thoracic spine, cerebrospinal fluid ("CSF") analysis, and an infectious disease ("ID") consult. Id. at 46-47.

Petitioner's MRIs and computerized tomography ("CT") scans were normal, as was her CSF. Pet. Ex. 3 at 58, 63-70, 154-57. Petitioner received intravenous antibiotics for a short period of time at the recommendation of an ID doctor. Id. at 58. The ID doctor noted that Petitioner might have had a "post-vaccination fever reaction," but that she remained afebrile for three days while off prednisone. Id. at 216. Although the differential diagnosis included possible serum sickness, Guillain-Barré syndrome ("GBS"), "post-vaccination syndrome," multiple sclerosis, and Lyme disease, the discharge summary noted that Petitioner's most likely diagnosis was "post-vaccination syndrome since the patient received [two] vaccinations at the same time at her workplace." Id. at 58, 240. She was advised to follow up with neurology for an electromyography ("EMG"). Id. at 58.

After discharge, on September 22, 2015, Petitioner returned to Dr. Theune and reported that she was still having fevers every two to three days, as well as muscle aches, headaches, and fatigue. Pet. Ex. 5 at 65-67. She had been off prednisone for a week. Id. at 65. Physical examination was normal. Id. at 66. Dr. Theune diagnosed her with "serum sickness due to drug" and referred her to immunology. Id. at 66-67.

On September 28, 2015, Petitioner presented to neurologist Nabil Yazgi, M.D., for joint pain and "pins and needles" in her hands and feet after Pneumovax 23. Pet. Ex. 6 at 7-12. Examination was normal except for decreased strength of 4+/5 in the extremities. Id. at 8-12. The assessment was post-vaccination syndrome and demyelinating neuropathy, and Dr. Yazgi used the International Classification of Diseases ("ICD") code[16] for GBS. Id. at 12. He ordered an EMG/nerve conduction study ("NCS"). Id.

On October 1, 2015, Petitioner presented to internist Maria Alfakir, M.D. Pet. Ex. 1 at 1-2. Petitioner complained of paresthesias in a stocking and glove distribution but denied muscle

[16] ICD codes are a standardized system used to code diseases, morbidity, and cause of death data. See Classification of Disease, Functioning, and Disability, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/nchs/icd/icd-10-cm/index.html (last visited Feb. 6, 2025).

weakness. Id. at 1. She also complained of daytime sleepiness, snoring at night, and "witnessed apneas during her sleep." Id. Petitioner's "[o]ngoing medical problems" included joint pain, being "very tired," a fever every two to three days, and "back pain, neck pain – DUE TO PNEUMONIA VACCINE (August.24.15)." Id. On examination, Petitioner had decreased sensation to touch and pain in a stocking and glove distribution, but the examination was otherwise normal. Id. at 2. The assessment was sleep apnea, daytime sleepiness, paresthesias, and demyelinating syndrome. Id. Dr. Alfakir referred Petitioner for an EMG and noted that she would address the possibility of obstructive sleep apnea and FM after the EMG. Id. Petitioner never returned to this physician.

An October 1, 2015 EMG/NCS was normal except for a mild right sensory median nerve demyelination consistent with carpal tunnel syndrome ("CTS").[17] Pet. Ex. 6 at 21-25.

On October 19, 2015, Petitioner followed up with Dr. Yazgi and still complained of myalgias and joint stiffness, which made it difficult to walk, as well as weakness and paresthesias. Pet. Ex. 6 at 1-6. Her examination was the same as the September 28, 2015 visit, and she had no pain with ROM of her neck and lumbar spine. Id. at 2-6. The assessment was post-vaccination syndrome, CTS, and arthralgia. Id. at 6.

The same day, Petitioner presented to rheumatologist Thomas Giangrasso, M.D. Pet. Ex. 9 at 9.[18] Dr. Giangrasso noted that Petitioner complained of generalized joint pain since a Pneumovax 23 vaccine eight weeks earlier. Id.

On November 16, 2015, Petitioner followed up with Dr. Yazgi and reported the same symptoms in addition to getting a fever once per week and hand swelling. Pet. Ex. 6 at 13-18. The examination was the same as the September 28, 2015 and October 19, 2015 visits. Id. at 14-18. The assessment remained post-vaccination syndrome, CTS, and arthralgia. Id. at 18. However, Dr. Yazgi used ICD codes for PMR and FM. Id. He referred Petitioner to an ID physician. Id.

On November 17, 2015, Petitioner returned to Dr. Giangrasso and reported pain in her hands, wrists, elbows, and lower back. Pet. Ex. 9 at 1. She was taking Meloxicam. Id.

On January 7, 2016, Petitioner presented to ID specialist Donald Allegra, M.D., for fevers since receiving Pneumovax 23. Pet. Ex. 7 at 7-10. Petitioner related her history of a reaction in her arm for about a week after Prevnar 13 and Menactra, and low-grade fevers, headache, poor sleep, and hives on her left arm for three weeks after Pneumovax 23. Id. at 8. Dr. Allegra noted that high white blood cell counts may have been due to steroids. Id. The

[17] Carpal tunnel syndrome is "an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow. Symptoms result from compression of the median nerve in the carpal tunnel." Carpal Tunnel Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110370 (last visited Feb. 6, 2025).

[18] The examination notes in Petitioner's Exhibit 9 are handwritten and difficult to decipher.

examination was normal and Petitioner was afebrile. Id. at 9. Dr. Allegra's assessment was CTS, FM, and post-vaccination fever. Id. at 7. Regarding FM, Dr. Allegra noted that Petitioner had trigger points in her shoulders and behind her elbows, a light sleep pattern, and "other classical symptoms." Id. at 7-8. He also noted that it was "possible that all of her symptoms [were] due to a post vaccination syndrome, although [four] months after her pneumococcal vaccine seems to be a long time for this reaction to persist for." Id. at 8.

On January 19, 2016, Petitioner returned to Dr. Giangrasso and reported that she was still having pain in her hands, wrists, and elbows, and that her jaw was swollen. Pet. Ex. 9 at 2.

Petitioner followed up with Dr. Allegra on January 28, 2016 and complained of anterior chest pain, as well as pain in her left wrist, hands, knees, elbows, and lower back, myalgias, and arthralgias. Pet. Ex. 7 at 4-6. She reported having temperatures of 100.5ºF to 101.7ºF since her last appointment. Id. at 5. Dr. Allegra noted, "[t]he prior pneumococcal vaccines may be coincidental or causative. It is unclear at this point, but the symptoms seem way out of proportion to both a physical exam[ination] and also to her lab work[.] I am not sure what [is] the cause of the intermittent fevers." Id. at 4. The assessment was joint pain, weight gain, and myalgia. Id. Dr. Allegra prescribed a trial of Celebrex and noted he would reach out to the vaccine manufacturers to see whether they had any reports of unusual post-vaccination syndrome. Id.

On February 18, 2016, Petitioner returned to Dr. Allegra and reported that Celebrex helped her back pain but none of the other symptoms, and it caused headaches. Pet. Ex. 7 at 1-3. Petitioner reported that she had "Pneumovax and [two] hours after her shot she developed aches and pains[,] nausea[,] tingling in her hands[,] she had hives on her left arm[,] and then fever and intense pain." Id. at 2. These symptoms "resolved about a month later but ever since then she has had these myalgias, low back pain, decreased memory[,] and arthralgias." Id. Petitioner now complained of diffuse body aches, low back pain, and decreased memory. Id. The assessment was anxiety, joint pain, and memory loss. Id. at 1. Dr. Allegra noted, "[t]he patient seems to have significant symptoms but her exam[ination] and other lab work is very normal[.] [S]he did have a temperature curve for [two] weeks and over that period of time she had only [two] temperatures over 100." Id. He prescribed Elavil and indicated they would "continue to try various things to treat her for possible [FM]." Id. He also noted that he discussed "her case with her rheumatologist and both of us feel that she did have a reaction to the pneumonia shots but she appears to have now a [FM] post reaction." Id. Dr. Allegra felt that Petitioner could return to work eventually. Id. He noted that he had reached out to the vaccine manufacturers and was waiting for a call back. Id.

On February 24, 2016, Petitioner presented to endocrinologist Esther Lee, M.D., and reported that "she ha[d] not been herself" since receiving Prevnar 13 in June 2015 and Pneumovax 23 in August 2015. Pet. Ex. 46 at 4. The assessment was fatigue and diffuse pain. Id. Petitioner's bloodwork was normal. Id. at 4, 7-11.

Between March and August 2016, Petitioner attended 17 acupuncture sessions. Pet. Ex. 12 at 1-18.

On April 19, 2016, Petitioner presented to rheumatologist Thomas Whalen, D.O.,[19] for pain and stiffness. Pet. Ex. 4 at 1-2. She reported her history of a local injection site reaction but no systemic symptoms after a June 29, 2015 Prevnar 13 vaccination. Id. at 1. However, she reported "a severe systemic reaction to [a] Pneumovax 23 injection on August 24, 2015." Id. She further reported that she was "diagnosed with what sound[ed] like a serum sickness like reaction," with symptoms of diffuse myalgias and arthralgias, fever, fatigue, chills, and headache. Id. Petitioner complained of continuing diffuse myalgias and arthralgias with variable low-grade fevers and extreme fatigue, as well as difficulty sleeping. Id. She also complained of daily, widespread pain which she described as constant and aching. Id. Her examination was normal, except for cervical ROM at 75% of normal, moderately decreased lumbar ROM with pain to palpation, minimally decreased shoulder ROM with pain and spasms of the trapezius, and 18/18 myofascial tender points/spasm. Id. at 2. Dr. Whalen's impression was "serum sickness like reaction to Pneumovax" with a sleep disorder and FM secondary to that diagnosis. Id. He noted, "[i]t is my opinion, within a reasonable degree of medical certainty, that the injuries listed above are a direct result of the trauma suffered on [August 24, 2015]." Id. Dr. Whalen prescribed a home exercise program and ordered a sleep study. Id. He also noted that Petitioner was totally disabled and "[u]nable to work due to sequelae of [the] Pneumovax injection." Id.

A May 5, 2016 sleep study was normal with no sleep disordered breathing or movement disorder. Pet. Ex. 5 at 69-76.

On May 9, 2016, rheumatologist and allergist/immunologist John Cohn, M.D., evaluated Petitioner as part of her workers' compensation case. Pet. Ex. 14 at 21-26. After reviewing Petitioner's records and her account of her medical history, Dr. Cohn noted that there was "not an established connection" between a vaccine reaction and development of FM, that he was "unable to identify [online] a description of a symptom complex similar to what she describe[d] as a result of pneumococcal vaccination," and that he could not "reach a conclusion to a reasonable degree of medical certainty that this unusual presentation [wa]s the result of a pneumococcal vaccination." Id. at 25-26. He also noted that none of the physicians whose records he had reviewed described a disabled patient, nor was Petitioner "overtly disabled" at the time of his examination. Id. at 26.

Petitioner returned to Dr. Whalen on July 21, 2016 and reported that she continued to improve with acupuncture, but still had discomfort in her left hand and wrist, which she described as tightness that was dull and aching, rated at as five out of ten. Pet. Ex. 4 at 3-4.

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[19] Petitioner was referred to Dr. Whalen by her workers' compensation attorney. Pet. Ex. 14 at 21. In December 2019, Dr. Whalen pleaded guilty to one count of healthcare fraud, one count of importation contrary to law, and two counts of distribution of controlled substances. Pennsylvania Doctor Pleads Guilty to Fraud and Drug Importation Charges, U.S. Dep't Just. (Dec. 17, 2019), https://www.justice.gov/opa/pr/pennsylvania-doctor-pleads-guilty-fraud-and-drug-importation-charges. His medical license currently appears to be on probation. Pennsylvania Licensing System (PALS), Dep't State, https://www.pals.pa.gov/#/page/search. (search for Thomas Whalen, license number OS004351L, Downingtown, Pennsylvania) (last visited Feb. 10, 2025).

On July 25, 2016, Petitioner presented to her obstetrician and gynecologist after a positive pregnancy test. Pet. Ex. 8 at 26-32.

Petitioner presented to Dr. Giangrasso on October 28, 2016 and reported that she was doing well and had no complaints. Pet. Ex. 9 at 4.

On February 15, 2017, Petitioner had a scheduled cesarean section at thirty-seven weeks. Pet. Ex. 10 at 5, 12-14, 21-23. Petitioner stated in her affidavit that all her symptoms resolved with her pregnancy and have not recurred. Pet. Ex. 11 at ¶ 33.

2. Petitioner's Sanofi Employee Health Records

Petitioner's employee health records show that she received Menactra and Prevnar 13 vaccinations on June 29, 2015. Resp. Ex. B at 1. Her next documented encounter was August 24, 2015, when she received her Pneumovax 23 vaccination. Id. There are no entries in the record between June 29 and August 24 about Petitioner experiencing any adverse reaction to her Menactra or Prevnar 13 vaccinations. See id.

On August 31, 2015, a document was received excusing Petitioner from work on August 25 to August 27 due to an "allergic reaction to pneumonia vaccine." Resp. Ex. B at 1. On September 8, 2015, the record stated "[r]eceived an update that [Petitioner] was admitted to hospital last [week with] possible [GBS]." Id. The next day, September 9, Nancy Fulmer phoned the Petitioner to check on her welfare. Id. Petitioner reported that "she noted hives on her left arm where she received the [P]neumovax 23 about [four to five] hours after the shot" and then she developed tingling in her fingers, fever, and headache. Id.

There are additional notes from subsequent phone calls from August 31, 2015 through November 16, 2015. Resp. Ex. B at 2-3. These notes do not reference the Prevnar 13 or Menactra vaccines. See id.

3. Petitioner's Affidavit

Petitioner executed an affidavit on April 27, 2018. Pet. Ex. 11. In it, she averred that on June 23, 2015, she began to work as a contract worker at a research facility operated by Sanofi, and as a condition of employment, she was required to receive vaccinations. Id. at ¶¶ 5-6. She received Menactra and Prevnar 13 vaccinations on June 29, 2015 at Sanofi. Id. at ¶ 7. "Shortly after" receiving the vaccinations, she averred that she developed hives on her left arm where the Prevnar 13 vaccine was administered. Id. at ¶ 8. She also developed pain and swelling, making it difficult to move her arm. Id. The "symptoms lased for about a week." Id. During this week, she had difficulty dressing and grooming herself, although she did not take sick leave from work. Id. Petitioner reported her reaction to the Lab Coordinator and was informed that her arm pain and swelling was "normal."[20] Id. at ¶ 9.

[20] This conversation is not reported in the Sanofi employee health records. See Resp. Ex. B.

The balance of Petitioner's affidavit relates to the Pneumovax 23 vaccination she received on August 24, 2015. See Pet. Ex. 11 at ¶¶ 10-32. Immediately after receiving the Pneumovax 23 vaccine, she had burning in her left arm, and then within two hours, she had "the same rash in her left arm, was nauseous[,] and became very fatigued." Id. at ¶ 13. The following day, she experienced fatigue, headaches, chills, pain in her neck and back, and tingling in her fingers. Id. at ¶ 14. She saw her PCP the next day, August 25, 2015, and that visit is described in her affidavit. Id. at ¶ 16.

Petitioner recounted her clinical course in 2015 and 2016, including the visits to the medical providers as reflected in her medical records. Pet. Ex. 11 at ¶¶ 16-32. When Petitioner became pregnant in 2016, all her symptoms "disappeared" and did not return. Id. at ¶ 33. Although she filed a Workers' Compensation Action,[21] she did not file a civil action regarding her alleged vaccine related injury. Id. at ¶ 34.

4. Petitioner's Deposition

A deposition of Petitioner was taken in her Workers' Compensation claim on April 27, 2016. Pet. Ex. 36 at 1. Petitioner holds a bachelor's degree in animal science and endocrine physiology from Rutgers University and a master's degree in biology. Id. at 6-7. She was a lab analyst at Sanofi during the events at issue. Id. at 7. She received Menactra and Prevnar 13 vaccinations on June 29, 2015, as a condition of her employment. Id. at 7-8.

Petitioner testified that she did not have a reaction to the Menactra vaccination but had "a pretty bad localized reaction to Prevnar 13" given in her left deltoid, and she was unable to move her arm for about a week. Pet. Ex. 36 at 8. She also had "raised hives." Id. She did not miss any time from work due to her reaction to the Prevnar 13 vaccination. Id. The entirety of the reaction lasted about "a week." Id.

Petitioner testified about the problems she experienced after the Pneumovax 23 vaccination on August 24, 2015, consistent with her affidavit testimony. Pet. Ex. 36 at 11-12.

The balance of her deposition relates to the events that occurred after she received the Pneumovax 23 vaccine as related to her workers' compensation claim. See generally Pet. Ex. 36.

5. Dr. Thomas Whalen's Deposition

Dr. Whalen's deposition in the workers' compensation case was taken July 25, 2016. Pet. Ex. 37 at 1. At the time of his deposition, he was a board-certified physician in the field of

[21] Petitioner's workers' compensation claim arising out of her alleged work injury related to her Pneumovax vaccine administered on August 24, 2015, was resolved by a settlement agreement. Pet. Ex. 14 at 3-10. Petitioner's employer, Day and Zimmerman, specifically denied liability for the alleged injury. Id. at 5-6.

internal medicine with a subspecialty in rheumatology. Id. at 7-8. He completed fellowships in rheumatology and immunology at the Cleveland Clinic and had practiced medicine since 1984. Id. at 8. Petitioner was referred to Dr. Whalen by her attorney for the purpose of obtaining an examination and preparing a report to address causation. Id. at 25. Dr. Whalen is not board certified in immunology. Id. at 27.

Dr. Whalen first saw Petitioner on April 19, 2016. Pet. Ex. 37 at 9. At that initial visit, Petitioner reported that "she developed a severe reaction to a Pneumovax 23 injection that she received on August 24, 2015." Id. Petitioner also reported a prior Prevnar 13 vaccination with "a local reaction at the injection site but no systemic symptoms." Id.

Dr. Whalen diagnosed Petitioner with a "serum sickness-like reaction to the Pneumovax" as well as a "sleep disorder" and a "[FM]-like syndrome secondary to the sleep changes." Pet. Ex. 37 at 16. He further opined that the Pneumovax 23 vaccination triggered these conditions. Id.

Dr. Whalen testified that while "local reactions" to vaccines were "not uncommon," systemic reactions were less common. Pet. Ex. 37 at 16-17. Dr. Whalen testified that after an individual has been vaccinated once, "the chance of having a more severe reaction increases by 10 to 15 percent." Id. at 17. Further, reactions that include "fever, headaches, diffuse body aches in areas unassociated with the local injection site are not uncommon and can occur in upwards of 25 to 30 percent of people" who have a "second vaccine." Id. However, Dr. Whalen noted that it was difficult to discern whether Petitioner had a "true serum sickness reaction, which had been reported with Pneumovax," because "she was treated with prednisone," which would render diagnostic testing invalid and "not worth doing." Id. He approved of her treatment with prednisone and noted that Petitioner improved with the treatment. Id. Dr. Whalen explained the mechanism of serum sickness as an immune mediated, "antigen antibody reaction" where immune complexes circulate and get "lodged in various tissues," causing symptoms consistent with the location of where the complexes are located. Id. at 17-18. Dr. Whalen specifically opined that the antigen in Petitioner's case was the Pneumovax vaccine. Id. at 18.

Dr. Whalen also briefly described his treatment of Petitioner. Pet. Ex. 37 at 18-22. As of the date of the deposition, July 25, 2016, Petitioner's FM seemed "pretty much resolved." Id. at 43.

6. Dr. John Cohn's Deposition[22]

Dr. Cohn is a medical doctor board certified in internal medicine, allergy and immunology, and pulmonary medicine. Pet. Ex. 42 at 5. He performed an independent medical examination of Petitioner on May 9, 2016. Id. at 14. His testimony was taken on July 20, 2016, in the Worker's Compensation matter. Id. at 1.

[22] Dr. Cohn's deposition was initially filed as Petitioner's Exhibit 38; however, the odd numbered pages were missing. His testimony was refiled as Petitioner's Exhibit 42, to include all pages of the transcript.

Dr. Cohn opined that the most common side effect of vaccination is a sore arm. Pet. Ex. 42 at 7. Less common effects include "not feeling well" and fever (usually low grade), and Dr. Cohn noted that all of these side effects are brief and self-limiting. Id. He testified that he had not previously seen the side effects reported by Petitioner here related to the Pneumovax 23 vaccine. Id.

Regarding the Prevnar 13 vaccination, Dr. Cohn testified that Petitioner reported she had a "large local reaction" and "couldn't move her arm for a week." Pet. Ex. 48 at 17. Petitioner complained to the nurse practitioner at work and was told that her "arm swelling was 'normal.'" Id. Petitioner's symptoms resolved by the end of the July 4th holiday. Id. at 17-18.

Moving to the Pneumovax 23 vaccination, Dr. Cohn noted that Petitioner reported that she had nausea and a "24 hour bug" the week before receiving the Pneumovax 23 vaccination on August 24, 2015. Pet. Ex. 42 at 13. Dr. Cohn then testified about Petitioner's account of her clinical course after receiving the Pneumovax vaccination and described his review of Petitioner's medical records. Id. at 18-49. Dr. Cohn testified that Petitioner reported that her physicians diagnosed her with FM. Id. at 29. Dr. Cohn disagreed that there was objective evidence to support a causal connection between the Pneumovax 23 vaccination and Petitioner's physical medical status. Id. at 50.

Dr. Cohn testified that serum sickness is no longer commonly seen after vaccination because gamma globulin is no longer given in tetanus vaccines. Pet. Ex. 42 at 75-76.

Dr. Cohn opined that after her Pneumovax 23 vaccination, he believed that Petitioner did not feel well for a couple of days and had a sore arm for a few days. Pet. Ex. 42 at 77. However, he testified there was a lack of evidence for "many of the complaints she had, other than the fever and a sore arm for a few days." Id. at 59.

D. Expert Reports

1. Petitioner's Expert, Dr. M. Eric Gershwin[23]

a. Background and Qualifications

Dr. Gershwin is board certified in internal medicine, rheumatology, and allergy and clinical immunology. Pet. Ex. 50 at 2. He completed his M.D. at Stanford University after which he completed an internship and residency in internal medicine at Tufts New England Medical Center and trained in immunology at the National Institutes of Health ("NIH") in Maryland. Id. at 1-2. He is currently a Distinguished Professor of Medicine in the Division of Rheumatology, Allergy, and Clinical Immunology at the University of California, Davis School of Medicine. Id. at 1. Dr. Gershwin has held various editor and reviewer positions on medical

[23] Petitioner filed two reports from Dr. Gershwin. Pet. Exs. 15, 48. Petitioner's Exhibit 15 was filed twice. It was first filed on August 16, 2019 (ECF 26) and refiled on January 6, 2021 (ECF 66).

journals, and he has authored or co-authored over 1,000 publications during his career. Id. at 5-143.

b. Diagnosis Opinion

Regarding diagnosis, Dr. Gershwin opined that Petitioner's "diffuse complaints [were] consistent with a pain threshold disorder of which [FM] is the most likely candidate." Pet. Ex. 48 at 1.

c. Causation Opinion

i. Althen Prongs One and Two

Dr. Gershwin combined his opinions about Petitioner's clinical course with those including his proposed causal mechanisms. See Pet. Ex. 15 at 2-3. Therefore, the undersigned discusses his opinions about Althen prongs one and two together. His casual theories are discussed in turn.

First, Dr. Gershwin stated Petitioner had "a local reaction to the vaccine." Pet. Ex. 15 at 2. However, he did not identify "the vaccine" or define what he meant by "local reaction." See id. In his summary of Petitioner's clinical course, Dr. Gershwin's reference to a "local reaction" appears to refer to the reactions she experienced in her left arm following her Prevnar 13 vaccination[24] on June 29, 2015. Id. at 1. Dr. Gershwin noted that Petitioner had a "similar rash" at the site of her vaccination on August 24, 2015. Id. Dr. Gershwin then explained that Petitioner's "local reaction" caused "pain, headaches, and psychosocial trauma which triggered a cascade of events leading to her [FM]." Id. at 2. He did not explain how a "local reaction" could cause headaches or psychosocial trauma nor did he did not define "psychosocial trauma." See id.

Next, Dr. Gershwin's opined that Petitioner was "over-doctor[ed]" and "over-treated." Pet. Ex. 15 at 2. She saw multiple physicians and underwent "extensive and unneeded laboratory tests." Id. Dr. Gershwin opined that because she was "over-treated," "over-doctored," and "over-medicat[ed]", Petitioner "continued to experience symptoms and developed [FM]." Id. Dr. Gershwin did not define the terms "over-doctored," "over-treatment," or "over-medicated." See id. And he did not explain how a vaccine or vaccines could cause over-treatment, or how over-treatment can cause FM. See id.

In his second report, he opined that the fact that Petitioner's "condition resolved after the birth of her child [] supports [his] opinion that her vaccine-related illness was due to how her vaccine reactions were treated by her physicians. The birth of her child took [her mind] off this issue." Pet. Ex. 48 at 2.

[24] Although Dr. Gershwin noted the dates of the vaccines, he did not identify the vaccines by name in his report. Pet. Ex. 15 at 1.

Dr. Gershwin's third casual idea is based on "stress response" and "chronic stress." Pet. Ex. 15 at 2. Dr. Gershwin opined that "[p]atients with FM have disturbances in [] [two] major interacting stress response systems." Id. These include the "autonomic nervous system and the hypothalamic-pituitary-adrenal (HPA) axis." Id. Dr. Gershwin briefly described the potential association between "hypofunctioning of the HPA axis" and FM.[25] Id. at 2-3. Although Dr. Gershwin acknowledged the association was "still debated," he suggested that "[t]he vaccine" created a "stress response" and that "[c]hronic stress might promote disturbances in the stress-response system that could lead to the development of symptoms of FM." Id. at 2. He did not state which vaccine or vaccines were implicated or explain how a vaccine could cause a "stress response." See id.

In support of his "stress response" theory, Dr. Gershwin cited several articles. See Pet. Ex. 15 at 2-3. An article by Arnold stated that "chronic stress might promote disturbances in the stress-response system that could lead to the development of symptoms of FM." Pet. Ex. 17 at 10. But Arnold did not identify vaccination as playing a role in the etiology of "chronic stress" or FM. See id. Further, Arnold used the word "might"[26] which suggests that this idea has not been accepted as a likely cause of FM.

In a 1997 article by Pillemer et al.,[27] the authors noted that FM "may be a 'stress-related illness' since its onset often coincides with physical or psychological stress." Pet. Ex. 18 at 4. They explained that "[a]dverse early experiences, including abuse, neglect, severe childhood illness, and associated medical treatment may influence vulnerabilities to a variety of physio- and psychopathologies, and possibly to disorders such as FM[]." Id. at 5; see also Pet. Ex. 27 at 9 (noting FM may be triggered or worsened by "physical trauma such as motor vehicle

[25] For more information about the HPA axis and potential neuroendocrine abnormalities in FM, see Pet. Ex. 20 at 2 (Gail K. Alder et. al., Neuroendocrine Abnormalities in Fibromyalgia, 6 Current Pain & Headache Rep. 289 (2002)). Some of Petitioner's medical literature also discuss decreased hypothalamic corticotropin-releasing hormone ("CFH"). See, e.g., Pet. Ex. 26 at 1-7 (George Chrousos & Philip Gold, The Concept of Stress and Stress System Disorders: Overview of Physical and Behavioral Homeostasis, 267 JAMA 1244 (1992)). All of Petitioner's articles have been reviewed but they are not all discussed because they relate to concepts that are beyond the scope of this Decision. Further, they do not support vaccine causation as there is no evidence that Petitioner had a neuroendocrine disorder at the time of her vaccinations on June 29, 2015, or that the vaccinations at issue caused a neuroendocrine disorder.

[26] The word "might" is "used to say that something is possible." Might, Merriam-Webster Dictionary Online, https://www.merriam-webster.com/dictionary/might (last visited Feb. 10, 2025). The possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. See, e.g., Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence).

[27] Stanley R. Pillemer et al., The Neuroscience and Endocrinology of Fibromyalgia, 40 Arthritis & Rheumatism 1928 (1997).

accident");[28] Pet. Ex. 28 at 5 tbl. 3 (precipitating factors of FM include "severe infectious illness, physical trauma, and severe emotional distress").[29] These articles do not identify vaccinations, or a local vaccine reaction lasting for one week, as the type of stressor event that could lead to the development of FM.

Dr. Gershwin's fourth idea is that "[h]eightened pain sensitivity is part of the development of [FM]." Pet. Ex. 15 at 3. He opined that Petitioner had a "heightened pain sensitization syndrome" in "response to her vaccination." Pet. Ex. 48 at 1. He did not identify which vaccine(s) were implicated. See id.; Pet. Ex. 15 at 3. He also noted that "modulation of pain-related information may be related to the onset and/or maintenance of chronic pain." Pet. Ex. 15 at 3 (citing Pet. Ex. 31).[30] He then referenced another phrase, "central sensitivity syndrome." Id. (citing Pet. Ex. 32;[31] Pet. Ex. 33;[32] Pet. Ex. 34).[33] Although he cited to several articles that discuss these phrases, Dr. Gershwin did not develop these concepts or explain how they are related to vaccination. See id. Without developing these concepts, he concluded that "this reaction, combined with [] over-treatment . . . is why it makes sense that [Petitioner] would develop [FM] after having a local reaction." Id.

In his second report, Dr. Gershwin argued that "over-doctoring" led "directly to a pain sensitization syndrome." Pet. Ex. 48 at 1. He stated that Petitioner's "heightened pain sensitization syndrome" was due to Petitioner's "misinterpretations of the severity of these reactions and the failure of her doctors that lead to her chronic pain." Id. Dr. Gershwin did not provide facts from Petitioner's medical care to support his conclusions, especially about what facts constituted examples of the "failure of her doctors" related to the medical care that Petitioner received. See id.

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[28] Daniel Clauw & George Chrousos, Chronic Pain and Fatigue Syndromes: Overlapping Clinical and Neuroendocrine Features and Potential Pathogenic Mechanisms, 4 Neuroimmunomodulation 134 (1997).

[29] Mark A. Demitrack & Leslie Crofford, Evidence for and Pathophysiologic Implications of Hypothalamic-Pituitary-Adrenal Axis Dysregulation in Fibromyalgia and Chronic Fatigue Syndrome, 840 Annals N.Y. Acad. Sci. 684 (1998).

[30] Roland Staud, Abnormal Pain Modulation in Patients with Spatially Distributed Chronic Pain: Fibromyalgia, 35 Rheumatic Disease Clinics N. Am. 236 (2009).

[31] Muhammad B. Yunus, Central Sensitivity Syndromes: A New Paradigm and Group Nosology for Fibromyalgia and Overlapping Conditions, and the Related Issue of Disease Versus Illness, 37 Seminars Arthritis & Rheumatism 339 (2008). This article was also filed as Petitioner's Exhibit 35.

[32] Muhammad B. Yunus, The Concept of Central Sensitivity Syndromes, in Fibromyalgia and Other Central Syndromes (Daniel Wallace & Daniel Clauw eds., 1st ed. 2005).

[33] Muhammad B. Yunus, Fibromyalgia and Overlapping Disorders: The Unifying Concept of Central Sensitivity Syndromes, 36 Seminars Arthritis & Rheumatism 339 (2007).

Fifth, Dr. Gershwin offered an opinion based on the idea that the vaccine Petitioner received on June 29 "'primed' her immunologically and psychologically for the development of [FM]." Pet. Ex. 15 at 3. "But for the initial adverse reaction to the June 29, 2015 [vaccine, Petitioner] would not have developed a worsening reaction followed by the development of [FM]." Id. He concluded that the Prevnar 13 vaccination administered to Petitioner in June 2015 "'sensitized' her immune system and produced the rash that was the initiating factor for her over-doctoring." Id.

He further contends that the "reintroduction" of that "very same antigen a few months later aggravated her already sensitized immune system causing a more serious adverse reaction results in the injuries" because the "booster vaccination in the left arm . . . was the same antigen" she received in the same arm in June. Pet. Ex. 15 at 3. According to Dr. Gershwin, the vaccine antigens given August 24, 2015, approximately two months after her early vaccines, "caused rapid degranulation and the release of inflammatory compounds, including histamine, which contribute to local inflammation." Id. He further asserted that this caused a severe adverse reaction which caused her injury. Id. Dr. Gershwin did not offer facts or evidence to support each assertion offered in this opinion. See id. He did not develop each assertion of this theory or its conclusion.

The sixth theory suggested by Dr. Gershwin relates to "immune cell activation" and "serum sickness." Pet. Ex. 15 at 3. He opined that Petitioner's June 29, 2015 Prevnar 13 vaccination contained an antigen which "caused an unnecessary immune response" that led to a rash and diagnoses of "post-vaccination syndrome" and "serum sickness." Id. He acknowledged that this was a "self-limiting serum sickness-like picture." Id. at 2. And he did not opine that Petitioner's "self-limiting serum sickness-like" condition led to her FM. See id. at 2-3. Instead, he stated that "[Petitioner] was [] essentially turned into a medical experiment" and referred to multiple specialists and over-doctored. Id. at 2. He does not define or explain "unnecessary immune response" or "serum sickness." See id. at 2-3.

Although Dr. Gershwin alleged Petitioner had an immune cell activation that "caused an unnecessary immune response" in his first report, he backed away from that opinion in his second report. See Pet. Ex. 15 at 3; Pet. Ex. 48 at 1. In the second report, Dr. Gershwin clarified that he was not arguing that Petitioner had an "immune-mediated" condition or that his theory is based on "mimicry" (presumably he is referencing molecular mimicry, an immune-mediated process). Pet. Ex. 48 at 1.

Dr. Gershwin's seventh theory relates to an immunoglobulin E ("IgE")-mediated allergic reaction. Pet. Ex. 15 at 3. Dr. Gershwin opined that Petitioner "received the booster vaccination in the left arm, which was the same arm she received the June 29, 2015 vaccine." Id. He goes on to say that "[t]he result of the injection caused a rapid binding of the antigen [] in the vaccine to IgE mast cells circulating in her left arm." Id. Further, the "result of the reintroduction [of] the vaccine antigen caused rapid degranulation and the release of inflammatory compounds, including histamine, which contribute to local inflammation." Id. In his second report, Dr. Gershwin again opined that Petitioner had an "allergic response to Prevnar," and he noted his opinion was "based on the rash and opinions of her treating physicians." Pet. Ex. 48 at 1.

Central to all of Dr. Gershwin's causal ideas is the notion that Petitioner did not receive appropriate medical care and that this lack of appropriate medical care caused her to develop FM. See, e.g., Pet. Ex. 15 at 2 ("[S]he was essentially turned into a medical experiment in which she was referred and went to multiple emergency rooms . . . [and] she developed [FM] as a result of over-doctoring and lack of counseling."); Pet. Ex. 48 at 1 ("It was [Petitioner's] misinterpretation of the severity of these reactions and the failures of her doctors that lead to her chronic pain."). He also asserted that she should have received counseling. Pet. Ex. 15 at 2 ("I should emphasize this again, [Petitioner] should have received counseling.").

In support of his opinion that Petitioner did not receive appropriate care, Dr. Gershwin again relied on Arnold. See Pet. Ex. 17; Pet. Updated Exhibit List, filed Dec. 22, 2023, at 6 (ECF Doc. 130) (noting Arnold "is used to support Dr. Gershwin's assertations that [Petitioner] did not receive the care she should have"). Arnold discussed the treatment of FM, stating that "treatment should be individualized for each patient . . . [and] includes [] identification and treatment of all symptoms or disorders . . . such as pain, fatigue, sleep disturbances[,] . . . and mood or anxiety disorders." Pet. Ex. 17 at 13. Medications may include antidepressants, anticonvulsants (for neuropathic pain), nonsteroidal anti-inflammatory drugs, and others. Id. at 14-21. Exercise should be encouraged and cognitive behavioral therapy can be helpful. Id. at 20-21. Support groups and group-based education has been reported as beneficial. Id. at 22. Alternative treatments such as acupuncture was also found to be effective. Id. Arnold, however, did not identify "counseling" as the gold standard treatment or suggest that "counseling" was an effective evidence-based treatment for FM. See id. at 13-23.

Dr. Gershwin cited 22 medical articles.[34] Notably, none of the articles discuss any association between "over-doctoring" and FM. Further, they do not discuss an association between vaccination and FM.

ii. Althen Prong Three

Dr. Gershwin opined that "[t]he timing between [Petitioner's] vaccination and the development of her local reaction is consistent with a temporal association and what one would expect from an IgE mediated reaction." Pet. Ex. 15 at 3. He did not identify what vaccine he was referencing when he offered this opinion. He did not define what he meant by "IgE mediated reaction." Id. Since Dr. Gershwin referenced the June 29, 2015 vaccination in the same paragraph, presumably his opinion related to the Prevnar 13 vaccination.

Dr. Gershwin did not specifically opine as to the onset of Petitioner's FM. Further, he did not provide an opinion about whether the onset of Petitioner's FM was appropriate based on his causal theories.

[34] Petitioner's exhibit 30 references a text about advances in Women's mental health, but the document itself was not filed.

2. Respondent's Expert, Dr. Mehrdad Matloubian[35]

a. Background and Qualifications

Dr. Matloubian is board certified in internal medicine and rheumatology. Resp Ex. E at 1-2. He holds a Ph.D. in virology/immunology. Id. at 1; Resp. Ex. D at 1. He received his Ph.D. and his M.D. from the University of California, Los Angeles after which he completed his fellowship, residency, and post-doctoral fellowship at the University of California, San Francisco. Resp. Ex. E at 1. He is currently an associate adjunct professor at the University of California, San Francisco. Id. He has an active rheumatology practice and is an associate director of the Molecular Medicine Consult Service. Id. at 3. Dr. Matloubian's research for the past 20 years has been focused on "innate and adaptive immune responses, including those of T and B cells, to acute and chronic viral infections." Resp. Ex. D at 1. He has published numerous peer-reviewed articles in these areas. Id.; Resp Ex. E at 10-14.

b. Diagnosis Opinion

Dr. Matloubian agreed that "[FM] or a chronic pain syndrome" was "an appropriate label for [P]etitioner's subjective complaints of diffuse muscle and joint pain." Resp. Ex. D at 10. He noted that FM is "a poorly defined entity within the chronic pain spectrum of diseases." Id. Further, Dr. Maloubian explained that the cause of FM is not known. Id.

c. Causation Opinion

i. Althen Prongs One and Two

Dr. Matloubian opined that Petitioner's FM was not caused by the Prevnar 13 vaccination she received on June 29, 2015. Resp. Ex. D at 13.

Dr. Matloubian interpreted Dr. Gershwin's theory as follows: Petitioner "developed an IgE mediated hypersensitivity (allergic) response to her Pneumovax immunization, which then led to development of [FM] through a vague and highly speculative mechanism" based on "'over-doctoring' and 'lack of counseling.'" Resp. Ex. D at 11 (citing Pet. Ex. 15 at 2). He further explained that "Dr. Gershwin believes that [P]etitioner's initial immunization with Prevnar 13 primed her for a more severe allergic response" to the Pneumovax 23 vaccination. Id.

Dr. Matloubian disagreed with Dr. Gershwin's opinion that Petitioner had an IgE-mediated allergic reaction to the Pneumovax 23 vaccination she received on August 24, 2015. Resp. Ex. D at 11. He explained that Dr. Gershwin based this opinion on Dr. Theune's August 25, 2015 note describing Petitioner's rash as "hives." Id. Although Dr. Matloubian agreed that a local injection site reaction can appear red with raised hive-like inflamed areas, he disagreed that this constituted "an allergic reaction." Id. According to Dr. Matloubian, hives due to an allergic reaction are usually itchy, resolve within 24 hours, and are not limited to the site of exposure to

[35] Respondent filed two expert reports from Dr. Matloubian. Resp. Exs. D, F.

an antigen, i.e. the injection site, but also occur in other places of the body. Id. Petitioner described her rash as painful instead of itchy, she did not complain of a rash on other parts of her body, and her rash lasted longer than one day. Id. There was "faint evidence" of the rash when she presented in the ED on September 5, 2015. Id. (citing Pet. Ex. 10 at 222). Because Petitioner's rash was not characteristic of hives associated with an allergic reaction, Dr. Matloubin opined it was "most likely" due to an "injection site reaction." Id.

Another reason that Dr. Matloubin disagreed that Petitioner had an IgE-mediated allergic reaction is because she reported that the onset began two hours after vaccination. Resp. Ex. D at 11. In contrast to Petitioner's reported rash onset, an IgE-mediated allergic reaction would be "rapid" and occur "within minutes after exposure to antigen or immunization." Id. Thus, it is described as an "immediate hypersensitive response." Id. Moreover, Dr. Matloubian explained that Petitioner did not have systemic manifestations of an IgE-mediated allergic reaction, including bronchospasm, difficulty breathing, low blood pressure, or anaphylaxis.[36] Id.

To support his opinion that Petitioner did not have an IgE-mediated allergic reaction to her Pneumovax 23 vaccination on August 24, 2015, Dr. Matloubian cited a text that defined and described hypersensitivity reactions. Resp. Ex. D at 11 (citing Resp. Ex. D, Tab 4).[37] IgE-mediated allergic reactions are defined as type I immediate hypersensitivity reactions that occur within minutes of exposure and are characterized by "[s]ystemic anaphylaxis, urticaria (hives), asthma, hay fever, allergic rhinitis, allergic conjunctivitis, atopic dermatitis (eczema), [and] angioedema." Resp. Ex. D, Tab 4 at 2 tbl.65-1, 2 tbl.65-2. These include "allergies to foreign substances such as food (e.g., nuts shellfish, eggs), pollen, penicillin, bee venom, or latex gloves." Id. at 2 tbl.65-2. The symptoms depend on "the route of entry of the allergen." Id. at 3. For example, a reaction to allergens in food may result in "swelling and itching of the lips, tongue, and throat." Id.

Instead of an allergic reaction, Dr. Matloubin opined that Petitioner had "an injection site reaction." Resp. Ex. D at 11. Injection site reactions are localized to the injection site, and may "appear red, raised, painful to touch and resemble hives, and interfere with arm movement." Resp. Ex. F at 1. While she had a rash, she also had systemic symptoms of nausea, fatigue, fever, fatigue, and neck and back pain that were "consistent with a typical [] reaction to the Pneumovax immunization." Resp. Ex. D at 11. Dr. Matloubian explained that Petitioner's injection site reaction was "self-limited." Resp. Ex. F at 1.

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[36] Anaphylaxis is a "hypersensitivity reaction in which exposure of a sensitized individual to a specific antigen or hapten results in [hives], [itching], and angioedema, followed by vascular collapse and shock and often accompanied by life-threatening respiratory distress." Anaphylaxis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition? id=2577 (last visited Feb. 5, 2025).

[37] Warren Levinson et al., Hypersensitivity (Allergy), in Review of Medical Microbiology & Immunology: A Guide to Clinical Infectious Diseases (Michael Weitz & Christina M. Thomas eds., 16th ed. 2020).

In support of his opinion that Petitioner had a self-limited injection site reaction, Dr. Matloubian provided several references. Resp. Ex. F at 1-2. Bonten et al.[38] studied 42,240 persons who received the Prevnar 13 vaccine as compared to a control group who received a placebo. Resp. Ex. D, Tab 1 at 1, 5. The study reported that local injection reactions were characterized by redness, swelling, pain, and limited ROM. Id. at 41-42, 42 fig.S3, 68-70 tbl.S13; see also Resp. Ex. D, Tab 2 at 3 (finding that Prevnar 13 vaccination was well tolerated with "[r]edness, swelling, pain, and limitation of arm movement" as the most frequently reported local reactions).[39]

In contrast to an injection site reaction, Stone et al.[40] described IgE-mediated allergic reactions, or immediate hypersensitivity, as the most "severe immediate reaction occurring after vaccination." Resp. Ex. D, Tab 5 at 2. Symptoms have a "rapid onset (typically <15 minutes) and include itching, urticaria, angioedema, nausea, vomiting, diarrhea, wheezing, shortness of breath, hypotension, loss of consciousness[,] and, in severe instances, death." Id. Treatment requires epinephrine. Id. Dr. Matloubian noted that Petitioner did not have these symptoms. Resp. Ex. F at 1. Petitioner's rash began several hours after vaccination, not within minutes, and she had pain that limited her arm movement, which is not characteristic of a hypersensitivity response. Id. at 2.

Next, Dr. Matloubian opined that Dr. Gershwin's assertion that the Prevnar 13 vaccine "primed" Petitioner's immune system was not feasible. Resp. Ex. D at 12. First, the vaccines have a different composition. Id. Prevnar 13 is "a conjugate vaccine that contains protein derived from diphtheria toxin," whereas Pneumovax 23, a polysaccharide vaccine, does not contain any protein. Id. Even if Petitioner developed an allergic response to Prevnar 13, since Pneumovax 23 does not contain protein, "it could not lead to an IgE-mediated immediate allergic response." Id. Therefore, Dr. Matloubian concluded that Dr. Gershwin's theory based on a "recall response to a protein antigen shared by both Prevnar 13 and Pneumovax cannot be correct." Id.

In his second report, Dr. Matloubian reiterated his disagreement that Petitioner's reaction to the Prevnar 13 vaccination in June 2015 primed or acted as a "prime boost" for Petitioner's reaction to the Pneumovax vaccination administered in August 2015. Resp. Ex. F at 2. He opined that Petitioner's reactions to both pneumococcal vaccinations were localized reactions and not IgE-mediated allergic reactions. Id. Therefore, there was no immune boost effect due to the Prevnar 13 vaccination and no immunological association between the two vaccinations. Id.

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[38] Marc J.M. Boten et al., Polysaccharide Conjugate Vaccine Against Pneumococcal Pneumonia in Adults, 371 New Eng. J. Med. 1114 (2015).

[39] K.A. Bryant et al., Immunogenicity and Safety of a 13-Valent Pneumococcal Conjugate Vaccine in Adults 18-49 Years of Age, Naive to 23-Valent Pneumococcal Polysaccharide Vaccine, 33 Vaccine 5854 (2015).

[40] Cosby A. Stone et al., Immune-Mediated Adverse Reactions to Vaccines, 85 Brit. J. Clinical Pharmacology 2694 (2019).

Third, Dr. Matloubian explained why he disagreed with Dr. Gershwin's opinion that Petitioner's FM was caused by a psychological response to an "anxiety disorder" or "over-doctoring." Resp. Ex. F at 2-3. Regarding an "illness anxiety disorder," Dr. Gershwin cited a medical article describing the condition; however, Dr. Matloubian explained the article did not discuss "whether 'over-doctoring' or 'failures to counsel[]' . . . leads to development of [FM] or illness anxiety disorder or hypochondriasis." Id. at 2 (citing Pet. Ex. 49).[41] Dr. Matloubian noted that Petitioner experienced physical pain, consistent with FM. Id. She was not diagnosed with an anxiety disorder or other psychiatric diagnosis. Id. To the extent that Dr. Gershwin was offering an opinion that Petitioner suffered from an anxiety disorder or any other psychiatric diagnosis, Dr. Matloubin observed that neither he nor Dr. Gershwin were qualified to offer such opinions because they are not psychiatrists. Id. Regardless, Dr. Matloubin noted that was no evidence in Petitioner's medical records to support the diagnosis of an illness anxiety disorder or other psychiatric condition. Id.

Dr. Matloubian also disagreed that Petitioner's records evidence that she was "over-doctored." Resp. Ex. F at 2. He opined that Petitioner sought medical care from health care providers in different medical specialties, which "is usually the case for an individual with an enigmatic condition like [FM]." Id. He further opined that Dr. Gershwin's assertion that medical care caused FM or a psychiatric illness "is not supported and purely speculative." Id. at 3.

Fourth, regarding Petitioner's complaints of prolonged fevers after the Pneumovax 23 vaccination, Dr. Matloubian noted that her physicians attributed these to a "serum sickness-like" reaction rather than an allergic reaction. Resp. Ex. D. at 11. Dr. Matloubin stated that there was no evidence, however, to suggest that Petitioner developed serum-sickness after her Prevnar 13 vaccination administered in June 2015. Id. at 12. Dr. Matloubian specifically disagreed that Petitioner sought treatment after her June 2015 vaccinations, or that she was diagnosed with any vaccine-related illness such as "post-vaccination syndrome" or "serum sickness" after her June vaccinations. Id. He cited an UpToDate publication by Wener,[42] stating that the "cardinal features of serum sickness are rash, fever, and polyarthralgias or polyarthritis, which begin one to two weeks after the first exposure . . . and resolve within a few weeks . . . . [T]he disease is self-limited, and prognosis is excellent . . . ." Resp. Ex. D, Tab 3 at 1.

Regardless of whether Petitioner's theory is based on serum sickness or IgE-mediated allergic reaction, Dr. Matloubian opined that Petitioner's "subsequent development of [FM] [was] more likely than not unrelated to her prior immunization with Prevnar on [June 29, 2015]." Resp. Ex. D at 13.

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[41] James L. Levenson, Illness Anxiety Disorder: Epidemiology, Clinical Presentation, Assessment, and Diagnosis, UpToDate, https://www.uptodate.com/contents/illness-anxiety-disorder-epidemiology-clinical-presentation-assessment-and-diagnosis (last updated Oct. 13, 2020).

[42] Mark H. Wener, Serum Sickness and Serum Sickness-Like Reactions, UpToDate, https://www.uptodate.com/contents/serum-sickness-and-serum-sickness-like-reactions (Franlast updated Feb. 5, 2021).

ii. Althen Prong Three

Dr. Matloubian noted that Petitioner reported pain at the injection site two hours after her Pneumovax 23 vaccination. Resp. Ex. D. at 12. The following days, she had fever, headache, neck pain, and back pain. Id. He opined that Petitioner's symptoms occurred "within the expected time frame for . . . typical reactions" to the Pneumovax 23 vaccine. Id. at 12-13. He further opined that the onset of Petitioner's reaction was not "within minutes" as would be expected for an IgE-mediated allergic reaction. Id. at 13.

He noted that on September 5, 2015, Petitioner went to the ED complaining of "an acute onset of diffuse joint and muscle aches," and these symptoms were later attributed to FM. Resp. Ex. D at 13. Since some of the symptoms she experienced the day after her Pneumovax 23 vaccine were like those associated with FM, Dr. Matloubian was unable to specifically determine the date of onset of her FM. Id.

Dr. Matloubian observed that Dr. Gershwin did not offer an opinion about the onset of Petitioner's FM, or whether such onset would be appropriate, regardless of whether it was based on serum sickness or an IgE-mediated allergic reaction. Resp. Ex. D at 13.

III. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The

received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records, "in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell ex rel. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less

deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded to medical records, special masters are not rigidly bound by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (noting Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received actually caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The special master must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

IV. FACTUAL DISPUTE ANALYSIS[43]

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is decided relative to the injury [,]" determining facts relating to the claimed injury can be significant. Id. Here, the parties agree that Petitioner was diagnosed with FM.

Respondent, however, identifies a dispute arising out of Petitioner's initial reaction to the Prevnar 13 and Pneumovax 23 vaccinations. Specifically, the question is whether Petitioner had a local injection site reaction or an IgE-mediated allergic reaction after her vaccinations.

The undersigned finds by preponderant evidence that Petitioner had a local injection site reaction and not an IgE-mediated allergic reaction to the Prevnar 13 vaccination. The medical records do not provide any evidence of an IgE-mediated allergic reaction after Petitioner's received her Prevnar 13 vaccine. There is no contemporaneous documentation of any reaction. Petitioner did not seek medical care or treatment. Approximately two months later, records dated August 25, 2015, document that Petitioner reported that after receiving her Prevnar 13 vaccination "her arm was extremely sore and she could not lift it without experiencing pain." Pet. Ex. 5 at 19. In the deposition for her workers' compensation claim given April 27, 2016, Petitioner described a "pretty bad localized reaction" to her Prevnar 13 vaccination. Pet. Ex. 36 at 8. She was unable to move her arm for about a week and she had "raised hives." Id. The reaction lasted about one week.

Based on the evidence, the undersigned finds that Petitioner had a reaction to her Prevnar 13 vaccination that was local to the injection site, characterized by "raised hives" at the site of her vaccination, and pain and swelling which made it difficult to move her arm. These symptoms lasted for approximately one week.

Dr. Gershwin's opinions about whether Petitioner had a IgE allergic reaction after Prevnar 13 are inconsistent and/or confusing. In his first report, Dr. Gershwin opined that

[43] The parties' dispute regarding onset and the undersigned's findings are discussed in the causation analysis below, relative to Althen prong three.

Petitioner had a "local reaction" to the vaccine, although he did not specify which vaccine. Pet. Ex. 15 at 1. He also opined that Petitioner had an "allergic reaction" to Prevnar. Pet. Ex. 48 at 1. His opinions are confusing in that he does not consistently identify what vaccine caused what reaction. Additionally, his opinions are difficult to understand because they are not well developed. He does not define the terms used in his reports or provide supportive medical literature to support his opinion that Petitioner had an IgE-mediated allergic reaction to her Prevnar 13 vaccine.

In contrast, Dr. Matloubian provided an explanation of IgE-mediated allergic reactions and supportive medical literature. Medical literature from Stone et al. corroborated Dr. Matloubian's opinion that Petitioner did not have an IgE-mediated reaction to Prevnar 13 because the evidence does not suggest her reaction began within 15 minutes of vaccination as would be expected with an allergic reaction. Further, she did not describe the allergic reaction symptoms of itching, angioedema, nausea, vomiting, diarrhea, wheezing, shortness of breath, low blood pressure, or altered or loss of consciousness. After her Prevnar 13 vaccination, she returned to work. She did not seek or require medical attention.

Therefore, based on the facts presented, the undersigned finds that preponderant evidence supports a finding that after her Prevnar 13 vaccination, Petitioner had a local injection site reaction to her vaccination.

Regardless of whether Petitioner had a local injection site reaction or an allergic reaction after her Prevnar 13 vaccination, Petitioner has failed to prove by preponderant evidence a causal theory or logical sequence of cause and effect (Althen prongs one and two) to explain how her Prevnar 13 vaccine caused her FM. See infra Section VI. Therefore, the undersigned notes that her Decision regarding entitlement does not turn on the nature of Petitioner's response to her Prevnar 13 vaccination.

The undersigned does not resolve the question of the nature of Petitioner's reaction after her Pneumovax 23 vaccination because under the Vaccine Injury Table, it is not a covered vaccine. See 42 C.F.R. § 100.3. Thus, the undersigned does not have statutory authority to resolve that dispute. § 12(a); see, e.g., Scanlon v. Sec'y of Health & Hum. Servs., No. 13-219V, 2013 WL 5755061, at *3 (Fed. Cl. Spec. Mstr. Sept. 27, 2013), aff'd, 114 Fed. Cl. 135 (2013) ("[A special master] has no authority to preside over a vaccine injury claim stemming from a vaccine not listed on the Vaccine Injury Table.").

V. SEVERITY REQUIRMENT

To receive compensation, Petitioner must also show that she

> (i) suffered the residual effects or complications of [her] illness, disability, injury, or condition for more than six months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§ 11(c)(1)(D).

Compensation is not available under the Vaccine Act for minor illness which are short-lived. Wright v. Sec'y of Health & Hum. Servs., 22 F.4th 999, 1001-04 (Fed. Cir. 2022). Cases may appropriately be dismissed for failure to substantiate the severity requirement. See, e.g., Hinnefeld v. Sec'y of Health & Hum. Servs., No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's GBS resolved less than two months after onset). It is Petitioner's burden to prove her case, including the six-month requirement, by a preponderance of the evidence. See § 13(a)(1)(A). To satisfy the six-month requirement, "[a] potential petitioner must do something more than merely submit a petition and an affidavit parroting the words of the statute." Faup v. Sec'y of Health & Hum. Servs., No. 12-87V, 2015 WL 443802, at *3 (quoting Black v. Sec'y of Health & Hum. Servs., 33 Fed. Cl. 546, 550 (1995), aff'd, 93 F.3d 784, 792 (Fed. Cir. 1996)). A petitioner cannot establish the length or ongoing nature of an injury merely through their own statements, but rather is required to "submit supporting documentation which reasonably demonstrates that the alleged injury or its sequelae lasted more than six months." Black, 33 Fed. Cl. at 550; see also Lett v. Sec'y of Health & Hum. Servs., 39 Fed. Cl. 259, 260-61 (1997) ("Section 300aa-13(a)(1) provides that a special master may not award compensation 'based on the claims of [a] petitioner alone, unsubstantiated by medical records or by medical opinion.'").

The Federal Circuit recently addressed the six-month severity requirement in Wright. 22 F.4th at 1001. The petitioner's child suffered immune thrombocytopenia purpura ("ITP"),[44] a condition characterized by abnormally low platelet counts, bruising, and bleeding, after receipt of the MMR vaccination. Id. The child's ITP resolved in less than three months, and although he had later episodes of bruising, testing showed that his platelet count remained normal. Id. at 1003-04. The Circuit held that the petitioner failed to satisfy the six-month requirement when the platelet count normalized less than three months post-ITP onset because "relatively non-invasive ongoing [platelet] monitoring" was not a "residual effect" pursuant to § 11(c)(1)(D)(i). Id. at 1001, 1003, 1006-07. The Circuit noted that the child's later bruising was not related to his vaccine injury and that ongoing testing "did not reveal, constitute, or cause any somatic change." Id. at 1001.

Defining the language in § 11(c)(1)(D)(i), the Circuit ruled that "[t]he term 'residual effects' . . . requires a change within the patient that is caused by the vaccine injury." Wright, 22 F.4th at 1004. It continued, stating that "'[r]esidual' suggests something remaining or left behind from a vaccine injury . . . . Because vaccine injuries are somatic conditions defined by their signs and symptoms within the patient, . . . their residues are similarly defined." Id. at 1005-06 (internal citations omitted). Further, the words "suffered" and "complication" in association with "residual effects" in § 11(c)(1)(D)(i) "suggest that Congress contemplated residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms."

[44] Immune thrombocytopenia purpura is "an autoimmune condition, caused by antigens against platelets, resulting in ecchymoses, petechiae, and other bleeding." Idiopathic purpura, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=101150 (last visited Feb. 5, 2025). The acute form of ITP "has a sudden onset, is more common in children, and often resolves spontaneously within a few months." Id.

Id. at 1006. The Circuit concluded that "[r]ead together, 'residual effects' and 'complications' appear to both refer to conditions within the patient, with 'residual effects' focused on lingering signs, symptoms, or sequelae characteristic of the course of the original vaccine injury, and 'complications' encompassing conditions that may not be 'essential part[s] of the disease' or may be outside the ordinary progression of the vaccine injury." Id.

Here, Petitioner received her Prevnar 13 vaccination on June 29, 2015. After vaccination, she did not seek treatment for any untoward reaction. There are no contemporaneous records evidencing that she experienced an adverse reaction. However, records from August 25, 2015, about two months later, document that after Petitioner's Prevnar 13 vaccine "her arm was extremely sore and she could not lift it without experiencing pain." Pet. Ex. 5 at 19. During her admission to the hospital in September 2015, Petitioner reported that she had received a vaccination in June that caused local soreness but no systemic symptoms.

In her workers' compensation deposition, Petitioner described a "pretty bad localized reaction" to her Prevnar 13 vaccination. Pet. Ex. 36 at 8. She was unable to move her arm for about a week and she had "raised hives." Id. The reaction lasted about one week.

Petitioner also filed an affidavit, executed in April 2018 three years after these events. In her affidavit, Petitioner averred that she developed hives at the site of her Prevnar 13 vaccination. She also developed pain and swelling, making it difficult to move her arm. The symptoms lasted about one week.

There is one inconsistent medical record dated August 31, 2015, where the history of present illness states Petitioner reported "[s]ince receiving Prevnar 13 [eight] weeks ago[,] [she] ha[d] developed swelling and pain in the [left upper extremity] at the inoculation [site] causing her to have occasional paresthesias in the fingertips and difficulty moving the arm." Pet. Ex. 2 at 34. The same records states that the Petitioner reported that her pain started "one week" before. Id. at 31. The record also states that the pain "started after getting vaccine per [patient] last week." Id. at 33. Onset of pain was "a few hours after receiving [P]neumovax [one] week ago she developed [a] headache, body aches[,] and hives associated with minimal chest and sinus congestion. [She] ha[d] had intermittent fevers since with constant headache and body aches." Id. at 34.

After reviewing all of the evidence, including medical records, deposition testimony, and affidavit, the undersigned finds that Petitioner had a reaction to her Prevnar 13 vaccination that was local in nature, characterized by "raised hives" at the site of her vaccination and pain and swelling which made it difficult to move her arm. These symptoms lasted for approximately one week, at which time they resolved. Petitioner's symptoms were not severe enough to require her to seek medical care, undergo diagnostic workup, or miss time from work. The reaction resolved after one week. There is no evidence that Petitioner experienced lingering effects after one week. There were no complications reported from this reaction.

Regarding the note on August 31 which relates symptoms back to the Prevnar 13 vaccine, the undersigned finds it to be internally inconsistent with the other evidence in the same record stating that Petitioner's symptoms lasted about one week. And it is also inconsistent with all of

the other evidence in the record. Considering and weighing all of the evidence, the undersigned finds it preponderates in favor of a finding that Petitioner's reaction to her Prevnar 13 vaccine was about one week.

Further, as discussed below, Petitioner has not proven that her reaction to the Prevnar 13 vaccination caused or contributed to her FM or any other injury.

In conclusion, the undersigned finds that Petitioner did not experience the side effects of her Prevnar 13 vaccination after approximately one week, and not for longer than six months. Therefore, she does not meet the severity requirement set forth in the Vaccine Act and her petition must be dismissed.

VI. CAUSATION ANALYSIS

A. Althen Prongs One and Two

Under Althen prong one, Petitioner must set forth a medical theory explaining how a covered vaccine—such as Prevnar 13—could have caused the sustained injury of FM. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 257 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds that Petitioner failed to provide preponderant evidence of a sound and reliable theory to explain how the Prevnar 13 vaccination can cause FM for the reasons discussed below. Because Pneumovax 23 is not a covered vaccine, the undersigned does not analyze or discuss whether it caused or contributed to Petitioner's alleged FM, as that question is outside the scope of the undersigned's jurisdiction under the Vaccine Act.

The gravamen of Dr. Gershwin's opinion is based on "over doctoring." He opines that Petitioner had an adverse reaction to her Prevnar 13 vaccination on June 29, 2015, that caused or contributed to inappropriate medical care or "over-doctoring" after her Pneumovax 23 vaccination on August 24, 2015, and that this "over doctoring" caused or contributed to Petitioner's FM.

As explained above, there is evidence that Petitioner had a reaction to her Prevnar 13 vaccination, and the undersigned finds that such reaction lasted one week. However, there is no

evidence that her one week reaction to Prevnar 13 caused any ongoing physiological, immune, or psychosocial process that could have impacted her response to the Pneumovax 23 vaccine. There are no records or diagnostic tests which evidence any residual effect of her Prevnar 13 vaccination beyond one week. Similarly, there is no evidence that Petitioner had any ongoing adverse effect from her Prevnar 13 vaccine as of the date that she received her non-covered vaccine.

Although Dr. Gershwin argues that the Prevnar 13 vaccination "primed" Petitioner that made her reaction to the Pneumovax 23 vaccine worse, he did not provide foundational evidence to support this proposition. There are no facts to show that Petitioner had an adverse immune or psychological response to the Prevnar 13 vaccine that lasted longer than one week. After one week, Petitioner did not continue to have any abnormal signs and symptoms reflecting an adverse or ongoing immunological response. She did not complain of any signs or symptoms of an adverse allergic reaction, psychosocial reaction, stress, or ongoing pain.

Further, Dr. Gershwin did not explain what he meant by "primed." Instead of providing a logical scientific explanation, he offered conclusory statements. He stated "[b]ut for the initial adverse reaction to the June 29, 2015 [vaccination] [Petitioner] would not have developed a worsening reaction followed by the development of [FM]." Pet. Ex. 15 at 3.

In summary, Dr. Gershwin did not cite to evidence to support his conclusion that Petitioner had an adverse reaction to her Prevnar 13 vaccination that "primed" her immune response so that it caused her to develop a "worsening reaction" after her Pneumovax 23 vaccine.

Even if Petitioner's Prevnar 13 vaccination did cause a more robust reaction to the Pneumovax 23 vaccination, Petitioner has failed to show that such a reaction can lead to FM. None of the medical literature he filed showed that either a local injection site reaction or allergic reaction can lead to a "cascade of events" that causes multiple physicians to over treat a patient, or that over treatment leads to FM.

As such, Dr. Gershwin's theory of causation is unsupported by medical or scientific facts, research, or any other reliable evidence. Moreover, his theory is speculative and/or conclusory in nature. When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. den'd, decision aff'd, 141 Fed. Cl. 138 (2018), aff'd, 945 F.3d 1362 (Fed. Cir. 2020). Special masters are expected to carefully scrutinize the reliability of each expert report submitted. Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592 F.3d at 1315). The undersigned will not rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Id.

Further, the undersigned finds Respondent's expert, Dr. Matloubian, and his opinions in this case more persuasive. Dr. Matloubian explained why Petitioner's reaction to the Prevnar 13 vaccine was a local injection site reaction rather than an allergic response, and he cited medical literature to support his opinions. He also discussed the prime-boost response to a vaccine and

the reasons why that did not occur here. Dr. Matloubin also explained that Prevnar 13 contains a protein which is not in the Pneumovax 23 vaccine.

The concept that a local or allergic vaccine site reaction can lead to over-doctoring which can cause FM is a novel concept, and the undersigned agrees with Dr. Matloubian that as a causal theory it is speculative. While the undersigned is aware of one case where Dr. Gershwin proposed a similar theory, the special master found that it did not support compensation under the Vaccine Act. In that case, as here, Dr. Gershwin alleged the petitioner saw multiple doctors and was overtreated. Cowart v. Sec'y of Health & Hum. Servs., No. 16-513V, 2021 WL 253977, at *10 (Fed. Cl. Spec. Mstr. Jan. 5, 2021). Special Master Moran noted that this opinion was conclusory, since Dr. Gershwin did not explain how visits to multiple physicians constituted over-treatment, or triggered a stress response, which could lead to FM. Id. The undersigned agrees that this opinion is conclusory, for the same reasons described by Special Master Moran.

In her Motion, Petitioner asserts that her FM "was caused by Psychosocial factors precipitated by the documented reactions to the vaccines." Pet. Mot. at 6. "The takeaway point is that [Petitioner] reacted to the first vaccine that primed her to fear reacting the same way to the second vaccine . . . . This second reaction was worse, and it confirmed her fears which sent her on an unfortunate journey to the development of [FM]." Id. at 6-7.

The assertion that Petitioner had fear arising out of her reaction to the Prevnar 13 vaccine, however, is not supported by the factual record. In her affidavit she described developing hives, pain, and swelling, making it difficult to move her arm, and these problems lasted about one week. While she explained that she had difficulty dressing and grooming herself, she was able to work that week and did not take sick leave. In her deposition she described having "a pretty bad localized reaction to Prevnar 13," and was unable to move her arm for about a week. Pet. Ex. 36 at 8. While Petitioner noted in her affidavit that she had "concerns" about receiving the Pneumovax 23 vaccine, she did not report that she was fearful or had undue anxiety or stress due to the Prevnar 13 vaccine reaction. Pet. Ex. 11 at ¶ 11. She did not describe experiencing stress or fear. She specifically stated that the reaction resolved after one week. And she did not state that she developed chronic stress due to her reaction to the Prevnar 13 vaccine.

Moreover, there are Vaccine Program cases with reasoned decisions finding that FM is not a compensable illness after vaccination. Although decisions of other special masters are not binding, the undersigned generally agrees with the reasoning of her colleagues in these cases. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

In Ruzicka, the special master denied entitlement where the petitioner alleged that a Tdap vaccination caused FM. Ruzicka v. Sec'y of Health & Hum. Servs., No. 17-109V, 2023 WL 8352496, at *1 (Fed. Cl. Spec. Mstr. Nov. 13, 2023). The special master noted that "FM is generally not considered to be an autoimmune disease, and thus unlikely to result from vaccination." Id. at *22. In Balasco and Fankhauser, the special master denied entitlement where the petitioner alleged the human papillomavirus ("HPV") vaccine caused FM. Balasco v. Sec'y of Health & Hum. Servs., No. 17-215V, 2020 WL 1240917, at *1 (Fed. Cl. Spec. Mstr. Feb. 14, 2020); Fankhauser v. Sec'y of Health & Hum. Servs., No. 09-590V, 2014 WL 7015509,

at *1 (Fed. Cl. Spec. Mstr. Nov. 24, 2014) (same). As described above in Cowart, the special master found that the petitioner did not establish FM was caused by overtreatment following a local reaction to the meningococcal vaccine. Cowart, 2021 WL 253977, at *1. In Doe/70, Doe/71, and Lee, the special master denied entitlement where the petitioner alleged FM was caused by the Hep B vaccine. Doe/70 v. Sec'y of Health & Hum. Servs., No. V, 2011 WL 539133, at *1 (Fed. Cl. Spec. Mstr. Feb. 9, 2011); Doe/71 v. Sec'y of Health & Hum. Servs., No. V, 2010 WL 2545721 (Fed. Cl. Spec. Mstr. May 26, 2010), mot. for rev. den'd, decision aff'd, 95 Fed. Cl. 598 (2010); Lee v. Sec'y of Health & Hum. Servs., No. 03-2479V, 2005 WL 1125672, at *1 (Fed. Cl. Spec. Mstr. Apr. 8, 2005). Recently, in Williams, the undersigned denied entitlement where petitioner alleged FM was caused by the influenza vaccine. Williams v. Sec'y of Health & Hum. Servs., No. 19-1269V, 2024 WL 5040482, at *1 (Fed. Cl. Nov. 13, 2024).

Overall, these cases illustrate the point that FM has not been shown by preponderant evidence to be a vaccine-related illness.

In addition, to satisfy Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether Althen prong two is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528 (Fed. Cir. 1993). While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the "diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court").

The undersigned finds that while several of Petitioner's treating physicians documented opinions about the reaction that Petitioner had following her Prevnar 13 vaccination, they did not opine that more likely than not her Prevnar 13 vaccination caused or contributed to her FM. On January 28, 2016, Dr. Allegra, ID physician, described Petitioner's symptoms of pain and stated that the "prior pneumococcal vaccines may be coincidental or causative . . . but the symptoms seem way out of proportion to both a physical exam[ination] and . . . lab work." Pet. Ex. 7 at 4. In this statement, Dr. Allegra considers causation but acknowledges the association between symptoms could be coincidental.

At the next visit, on February 18, 2016, Dr. Allegra wrote that he discussed the case with the rheumatologist and "both of us feel that she did have a reaction to the pneumonia shots but

she appears to have now a [FM] post reaction." Pet. Ex. 7 at 1. Here, Dr. Allegra opines that Petitioner had a vaccine reaction, but he appears to distinguish her FM symptoms as a different entity. The undersigned does not interpret this sentence as an opinion that the Prevnar 13 vaccine caused Petitioner's FM.

Lastly, the undersigned finds there is not preponderant evidence of a logical sequence of cause and effect between Petitioner's Prevnar 13 vaccine and her diagnosis of FM. Petitioner has failed to show by preponderant evidence that the reaction she experienced to her Prevnar 13 vaccine caused her to sustain a more severe reaction to her Pneumovax 23 vaccine as described above. Therefore, she had failed to provide a logical sequence of cause and effect showing that her Prevnar 13 vaccine directly or indirectly contributed to her reaction to the Pneumovax 23 vaccine, her clinical course afterwards, or her FM.

In summary, Petitioner has failed to offer a sound and reliable medical theory to show by preponderant evidence that her Prevnar 13 vaccine caused or contributed to her FM. Moreover, the undersigned finds that Petitioner failed to provide preponderant evidence of a logical sequence of cause and effect. Thus, Petitioner has failed to satisfy Althen prongs one and two.

B. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a "medically acceptable temporal relationship." Id. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged under Althen prong one. Id.; see also Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243-44 (Fed. Cir. 2014); Shapiro., 101 Fed. Cl. at 542. Thus, prong three contains two parts: first, Petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, they must demonstrate that the onset of the disease occurred in this period. Shapiro, 101 Fed. Cl. at 542-43.

Because Althen prong three coincides with Althen prong one, Petitioner's inability to meet her burden demonstrating how the Prevnar 13 vaccine can cause FM effectively precludes her from being able to meet her burden under the third Althen prong. Since the undersigned found that Petitioner did not offer a sound and reliable theory of causation, Petitioner cannot demonstrate that her FM arose in a medically acceptable timeframe pursuant to that theory. Even if Petitioner satisfied Althen prong three, that alone would not satisfy Petitioner's overall burden of proof. Veryzer v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury."). However, Petitioner's showing with respect to the third Althen prong is deficient.

Petitioner received her Prevnar 13 vaccine on June 29, 2015. She had a reaction to that vaccine for about one week. On September 5, 2015, she reported diffuse joint and muscle aches

that were later diagnosed as FM. Therefore, the undersigned finds onset of her FM symptoms began approximately September 5, 2015, more than two months after her Prevnar 13 vaccination.

Petitioner, through her expert, Dr. Gershwin, did not offer an opinion about whether a two month onset of FM was appropriate based on his theory of causation. Thus, the undersigned finds Petitioner failed to provide preponderant evidence of Althen prong three.

VII. CONCLUSION

The undersigned extends her sympathy to Petitioner for the health problems she experienced after vaccination. The undersigned's Decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

For the reasons discussed above, the undersigned finds that Petitioner has failed to establish by preponderant evidence that Prevnar 13 or Menactra vaccines she received on June 29, 2015 caused her FM or any other compensable injury. Further, Petitioner has failed to prove that the duration of her reaction to the Prevnar 13 vaccination was greater than approximately one week. Therefore, her Petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master